

Remarks

Applicant and the undersigned reviewed the Office Action carefully before preparing this response. Reconsideration is respectfully requested. Nonetheless, in light of the positions presented herein, this application is believed to be in condition for allowance.

The Examiner rejected Claims 31, 34 and 36 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention. In particular, the Examiner rejected use of the trademarks Zofran, Pepcid, Hydergine, Dramamine and Compazine in each of the cited claims. Accordingly, the Applicant has amended Claims 31, 34 and 36 to recite the generic name for each of these drugs.

In addition, the Examiner rejected Claims 1-36 under 35 U.S.C. 103(a) as being unpatentable over Hellstrom alone or in combination with Belgian Patent BE 637363A. The Examiner states that the particular active agent, the size and shape of the backing member, and the form of medication (i.e. a powdered medication attached directly to the card) are not critical. It is the position of the Examiner that modification of the Hellstrom reference to achieve these limitations/features of the present invention would be routinely determined by one of ordinary skill in the art through minimal experimentation.

U.S. Patent 3,540,579 ("Hellstrom") teaches a medication package having a relatively rigid backing member and a frangible membrane for dispensing a medication pill or tablet therefrom. In particular, the package is designed to permit the medication to be dispensed or released using one hand (see, for example, col. 3, lines 11-12). In order to accomplish this important function, the structural strength of the backing member is greater than that of the frangible membrane so that the membrane breaks when the backing member is angulated (or bent to the extent that the backing member forms an angle) (see col. 3, lines 46-49). Thus, medication is dispensed or released from the Hellstrom package by folding or otherwise angulating the backing member to nearly a 90-degree angle and rupturing the membrane. This action causes the covering membrane to rupture and brake, forcing the medication out of the package.

The Hellstrom medication package dispenses a medication in tablet or pill form. As illustrated in Figures 1-11a, 13-24, and 26-28a, the tablet is held between the backing member and the frangible cover. The cover is stretched over the pill and is sealingly joined

to the backing member. Together the backing and the cover retain the medication within the package. When medication is dispensed from the Hellstrom package, it comes out, or more precisely, is forced out of the package by angulation of the backing member (see, for example, Fig. 3). The Hellstrom reference also describes a medication package for dispensing freely flowing materials such as liquids, semi-liquids or powders. However, this configuration is taught only with respect to an additional cup member used to dispense the medication from the package. As in the primary embodiment, the medication is released from the package by folding the backing member and rupturing the covering membrane – the powder or liquid is not contained or applied directly to the backing member.

In light of the preceding, it is respectfully suggested that the Hellstrom reference is an inappropriate reference on which to base an obviousness rejection. The primary purpose of Hellstrom is to provide dispensing package. Within the package, a pill (or other object) is freely or loosely held between the backing member and the breakable membrane. The Hellstrom medication package does not disclose a medication that is contained or coated directly on to a surface of a base, applied directly to a surface of a base, or otherwise retained by the backing member alone. The package of Hellstrom merely retains the medication until the medication is dispensed.

There is no suggestion or motivation in Hellstrom for a package having a base containing medication thereon, or a medication applied to a base, as recited in Claims 1, 5, 13, 34 and 36 of the present invention. Clearly, the medication in Hellstrom is completely separate from, and not bound or applied to, any portion of the package's components or structure. Indeed, this configuration permits the Hellstrom package to dispense (and freely release) medication using only one hand. More specifically, Hellstrom does not teach or suggest a powder formulation that is applied directly to and retained by a base or surface with the use of a binding agent. Further, there is no suggestion or motivation in Hellstrom for a powdered or gelled medication form that is applied directly to or contained directly on a base or surface. Thus, the Hellstrom reference specifically teaches away from both a base containing medication thereon or a medication applied to the base, and thus, teaches away from the Applicant's invention.

Further, Claims 1, 5 and 13 recite a removable cover. However, there is simply no suggestion or motivation in Hellstrom for a removable cover since Hellstrom teaches a membrane covering which must be ruptured to dispense the medication pill, tablet or cup –

which is undeniably the heart Hellstrom medication dispensing package. Accordingly, the Hellstrom reference also teaches away from a removable cover, and therefore, teaches away from the present invention.

In addition, the Hellstrom package provides a wholly different method for delivering or administering medication than the methods of the present invention. When dispensed from the Hellstrom package, the pill or object comes out (or is forced out) of the package and released to the user. The form of the medication described in Hellstrom and the resulting method of delivery of the medication does not teach or suggest medication that is applied directly to or contained directly on a card surface and which is delivered or administered either by contacting the surface or solubly removing the medication from the surface, as recited in Claims 21, 25, and 31. Rather, and as stated herein, the Hellstrom reference dispenses medication in a completely alternate manner than the present invention by completely dispensing the pill from the packaging upon angulation of the backing member. Accordingly, use of the Hellstrom package clearly teaches away from the present methods.

Moreover, the proposed modifications suggested by the Examiner change the principal operation of the Hellstrom reference, and therefore, destroy the intended function of the Hellstrom invention, thus, rendering the Hellstrom package unsatisfactory for its intended purpose. "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 21 USPQ 1125 (Fed. Cir. 1984). Specifically, the Hellstrom patent specifically teaches a medication package which dispenses/releases medication (see col. 3, lines 9-17). To accomplish this function, Hellstrom teaches utilizing a backing member that is designed to fold and a covering that is designed to break to forcibly dispense the medication tablet or other object – again, critical features of the Hellstrom invention.

However, the Examiner suggests that binding a drug in particulate form directly to the Hellstrom backing member is obvious to those skilled in the art. The Applicant respectfully disagrees. In this proposed configuration, angulation of the Hellstrom backing member may break the frangible cover, but such action would not dispense or release the medication from the package, as further action by the user would be required to administer a dose. Certainly, the medication is not dispensed from such a package using only one hand. If the medication was in granular form and retained within a shallow recess on the Hellstrom backing member,

angulation of the backing member would rupture the frangible membrane but still not dispense the medication in the manner taught by the Hellstrom reference. Rather, such angulation would likely cause the medication to be haphazardly released or otherwise spilled from the package, and thus, ineffectively dispensing the medication. Clearly, the modifications suggested by the Examiner require substantial redesign of the elements shown in the Hellstrom reference, as well as change the basic principle under which the Hellstrom medication package was designed to operate. For these reasons, it is asserted that the Applicant's invention not obvious in light of Hellstrom.

In light of the foregoing, Applicant respectfully disagrees with the Examiner's assertion that Claims 1-36 are obvious in light of Hellstrom because there is simply no motivation in Hellstrom or the art to modify Hellstrom to achieve the Applicant's invention. Accordingly, the Examiner has not established a prima facie case of obviousness. Therefore, Applicant believes Claims 1-36 are in condition for allowance.

The Examiner also rejected Claims 1-36 under 35 U.S.C. § 103(a) as being unpatentable over Hellstrom in combination with BE 637363A. As stated herein, Hellstrom describes a medication dispensing package having a backing member and a membrane that releases a pill by forcing the pill through the frangible membrane. Contrary to Hellstrom, BE 637363A discloses medicament compositions that are impregnated or absorbed into paper, or alternatively contained within a paper pulp base which is then dried. The dosage units (i.e. the stamp-like portions) must completely ingested by the user to administer a dose of active drug. The paper sheets are flexible, and do not contain any form of covering or protection of the medication.

It is respectfully suggested that the cited combination and rationale is inconsistent with either reference. For instance, Hellstrom provides a package that dispenses pills. In contrast, BE 637363A recites a medication composition, in the form of paper, that delivers medication through ingestion of the paper composition. As stated herein, if an active agent (powdered, granulated, or liquefied) was attached to the Hellstrom backing member, as the Examiner suggests, Hellstrom would no longer dispense a medication through angulation of the backing member. BE 637363A, teaches away from by describing a medication composition that is ingested, and does not describe a package for dispensing or releasing medication in the form of a pill, as in Hellstrom. Thus, not only is such modification not suggested or taught by either reference, there is no motivation to make such a combination, as

such a modification clearly destroys the intended function of both the Hellstrom package and the medication compositions of BE 637363A.

Accordingly, Hellstrom taken alone or in combination with BE 637363A does not teach or suggest a base containing medication, or a medication applied to the base, as recited in Claims 1, 5, 13, 34 and 36. More specifically, the combination of Hellstrom with BE 637363A does not teach or suggest a powder formulation that is applied directly to, contained directly on, or independent retained by a base or surface. Further, unlike Claims 1, 5 and 13, there is no suggestion or motivation in either reference for a removable cover.

Moreover, BE 637363A represents a totally divergent method for delivering a medication than that taught by the Hellstrom reference, or the Applicant's invention as recited in Claims 21, 25 and 31. Instead, the Examiner proposes several steps in and diversions from Hellstrom to derive the Applicant's invention. Most notably, the Hellstrom dispensing method is stopped midpoint and switched to another completely different dispensing method, providing a divergent result (dispensing a pill into the hand of the user versus dispensing medication by contacting or solubly removing it using a card surface). Switching back and forth between divergent methods is neither taught or suggested by Hellstrom. There is simply no teaching, suggestion or motivation in Hellstrom to completely alter the functionality and utility of the backing member and frangible cover package in view of BE 637363A (a medication composition that is ingested by a user for administration of a dose) that renders the present invention obvious.

Neither Hellstrom nor BE 637363A, alone or in combination with the other, disclose or suggest the Applicant's invention. There is no motivation in either reference or the art for such a combination. Rather, for the reasons stated above, each reference teaches away from each other, and thus, provide an inappropriate combination on which to base obviousness. The rejection should be withdrawn, and Claims 1-36 should be permitted to proceed to issue.

The Applicant respectfully asserts that the § 103 obviousness rejections of the present claims are based on improper hindsight reasoning. The Examiner has used the highly innovative and novel solution taught by the Applicant as a blueprint, with the Hellstrom reference as the main structural diagram, and looked to other prior art for individual elements present in the claims but missing from the primary reference. In addition, focusing on the obviousness of substitutions and differences instead of the invention as whole is an improper way to make a determination of obviousness. This approach has been uniformly and

consistently rejected by the Federal Circuit and in doing so the Examiner disregards the statutory mandate that the invention be viewed "as a whole."

"In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious" MPEP § 2141.02 (internal citations omitted). In particular, the Examiner has distilled the Applicant's invention down to the "gist" of the invention, namely, the general concept of a backing member, an active formulation and a film covering, and thus, completely disregards express limitations present in the Applicant's claims.

Accordingly, Claims 1-36 are believed to be in condition for allowance. Consistent therewith, a favorable action is respectfully requested. The Examiner is invited to contact the undersigned by telephone should any issue remain. Thank you for your help and consideration.

Respectfully submitted,

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